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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,031	12/11/2003	Robert Zaczek	BMS-PH-7048-A(C)	8984
909	7590	02/08/2005	EXAMINER	
PILLSBURY WINTHROP, LLP			JONES, DAMERON LEVEST	
P.O. BOX 10500				
MCLEAN, VA 22102			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/734,031

Applicant(s)

ZACZEK ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-76 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **RESTRICTION INTO GROUPS**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-18, drawn to a method of screening inhibitors of beta amyloid comprising presenilin-1, classified in class 424, subclass 9.2.
  - II. Claims 1-18, drawn to a method of screening inhibitors of beta amyloid comprising presenilin-2, classified in class 424, subclass 9.2.
  - III. Claims 1-18, drawn to a method of screening inhibitors of beta amyloid comprising beta-secretase, classified in class 424, subclass 9.2.
  - IV. Claims 1-18, drawn to a method of screening inhibitors of beta amyloid comprising alpha secretase, classified in class 424, subclass 9.2.
  - V. Claims 1-18, drawn to a method of screening inhibitors of beta amyloid comprising gamma secretase, classified in class 424, subclass 9.2.
  - VI. Claims 1-18, drawn to a method of screening inhibitors of beta amyloid comprising BACE/memapsin-2, classified in class 424, subclass 9.2.
  - VII. Claims 19-24 and 26, drawn to a method of identifying a macromolecule inhibitor comprising a compound of Formula I-7T, classified in class 252, subclass 380+.
  - VIII. Claims 19-23, 25, and 26, drawn to a method of identifying a macromolecule inhibitor comprising a compound of Formula I-43T, classified in class 252, subclass 380+.

- IX. Claims 19-23, 26, and 27, drawn to a method of identifying a macromolecule inhibitor comprising compounds of Formula I-11T, classified in class 252, subclass 380+.
- X. Claims 28-31, 36-40, and 43-47, drawn to an inhibitor/macromolecule comprising a compound of Formula I-7T, classified in class 252, subclass 380+.
- XI. Claims 28-30 and 32, drawn to an inhibitor/macromolecule comprising a compound of Formula I-11T, classified in class 252, subclass 380+.
- XII. Claims 28-30, 33, 36-38, 41-45, 48, and 49, drawn to an inhibitor/macromolecule comprising a compound of Formula I-43T, classified in class 252, subclass 380+.
- XIII. Claims 28-30 and 34, drawn to an inhibitor/macromolecule comprising presenilin-1 or a fragment thereof, classified in class 252, subclass 380+.
- XIV. Claims 28-30 and 35, drawn to an inhibitor/macromolecule comprising presenilin-2 or a fragment thereof, classified in class 252, subclass 380+.
- XV. Claims 50-53, drawn to a method of identifying inhibitors, classified in class 252, subclass 380+.
- XVI. Claims 54-58, drawn to a method of treating Alzheimer, classified in class 424, subclass 9.1.
- XVII. Claims 59-70, drawn to a method of imaging, classified in class 424, subclass 9.3.

XVIII. Claims 71-76, drawn to a radiolabeled inhibitor of beta amyloid, classified in class 424, subclass 1.73.

**Notes:** Claims appearing in more than one group will only be examined to the extent that they read on the elected invention.

2. The inventions are distinct, each from the other because of the following reasons: Inventions (X-XIV and XVIII) and (I-IX and XV-XVII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the various products may be use in other methods such as in a method of screening inhibitors, a method of identifying macromolecules, a method of treating Alzheimer, or a method of diagnostic imaging.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

#### **ELECTION OF SPECIES**

4. Claims 1-76 are generic to a plurality of disclosed patentably distinct species comprising inhibitors/macromolecules. In particular, the inventions contain multiple

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products and uses thereof. In addition, the inhibitors/macromolecules may comprise compounds having Formulae I-7T, I-11T, or I-43T or presenilin-1, presenilin-2, beta secretase, alpha secretase, gamma secretase, or BACE/memapsin-2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**Note:** *The Examiner respectfully requests that the Applicant elect the appropriate inhibitor or macromolecule and/or assign each variable the appropriate value when electing a species (i.e., X = hydrogen; Z = nitrogen; Y = -CH<sub>3</sub>; etc.) and state which claims are drawn to the elected species.*

5. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. A telephone call was not made to request an oral election to the above restriction requirement due to the complexity of the restriction requirement.


7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1616

February 7, 2005